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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/445,480	JONGSMA ET AL.	
	Examiner	Art Unit	
	Anne Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2002 and 29 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-14 and 16-39* is/are pending in the application.

4a) Of the above claim(s) *1-7, 19-23 and 25-26* is/are withdrawn from consideration.

5)☒ Claim(s) *27* is/are allowed.

6)☒ Claim(s) *8, 10-14, 16-18, 24 and 28-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendments to the specification and claims 8, 10-14 and 16-18, the cancellation of claims 9 and 15 and the addition of new claims 24-33 requested in Paper No. 19, filed 15 October 2002, have been entered. The amendments to the specification and the addition of new claims 3439 requested in Paper No.21, filed 29 November 2002, have been entered. Claims 1-8, 10-14 and 16-39 are pending.

2. This application contains claims 1-7 and 19-23 drawn to an invention nonelected with traverse in Paper No. 17. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

3. Newly submitted claims 25-26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention in claims 25-26, a method of protecting a plant by inserting a protein into the plant, is independent and distinct from the elected method, which is a method of protecting a plant by transformation with a nucleic acid. The different methods have different starting materials, different method steps, and different end products.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25-26 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Applicant urges in the response filed 15 October 2002 that the Examiner must consider any foreign patent that is not in Applicant's control. This is not persuasive. An examiner must only consider the portions of a foreign patent that are in English (see MPEP 609). None of German Parent No. 0348348 is in English. Thus, the instant application could not be considered in view of this reference.

6. The drawings are objected to for the reasons indicated on the accompanying form PTO 948. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

7. The abstract is not descriptive of the instant invention. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The elected claims are drawn to a method of protecting a plant by transformation with a nucleic acid encoding a cysteine protease inhibitor. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

8. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from the specification, pg 12, lines 14-27, pg 18, lines 18-20 and 33-34, pg 20, lines 3-4, pg39, lines 13-14, pg 43, lines 13-14, pg 63, line 7, the Brief Description of the Drawings for Figures 1 and 2, and Table 12.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules

and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Claim Rejections - 35 USC § 112

9. Claims 8, 10-14, 17-18 remain rejected and claims 24 and 28-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 10 September 2002, as applied to claims 8-15 and 17-18. Applicant's arguments filed 15 October 2002 have been fully considered but they are not persuasive.

Applicant urges that one of skill in the art would be able to isolate further nucleic acids that encode cysteine protease inhibitors with type I thyroglobulin domains. Applicant cites US Patent 6,312,913, but did not send it (response pg 12).

This is not found persuasive. The specification fails to describe the structural features (*i.e.*, the sequence) of the other nucleic acids that encode such proteins. Applicant's arguments are drawn to enablement, not written description.

10. Claim 16 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 10

September 2002. Applicant's arguments filed 15 October 2002 have been fully considered but they are not persuasive.

Applicant urges that plasmid CAB1 is not essential to the claimed invention. Applicant urges that the starting plasmid is common and known in the art. Applicant will provide references so stating (response pg 12).

This is not found persuasive because Applicant is claiming an expression vehicle that is pCAB1. The exact sequence of the pCAB1 plasmid is not disclosed in the specification. It is not clear from the specification on pg 59-60 if the plasmid encodes equistatin. Because this plasmid cannot be made using the guidance in the specification and is essential to the invention, it must be deposited.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
(e) the deposit will be replaced if it should ever become inviable.

11. Claims 8, 10-14, 17-18 remain rejected and claims 24 and 28-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of protecting a plant against insect or nematode infestation by transformation with a nucleic acid encoding equistatin, does not reasonably provide enablement for a method of protecting a plant against insect or nematode infestation by transformation with a nucleic acid encoding a cysteine protease inhibitor comprising a type I thyroglobulin domain or encoding a functional fragment of a such a protein or equistatin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 10 September 2002, as applied to claims 8-15 and 17-18. Applicant's arguments filed 15 October 2002 have been fully considered but they are not persuasive.

Applicant urges that the description of the claimed process and the working examples would enable one of skill in the art, without undue experimentation, to isolate the nucleic acids as claimed and use them in the method (response pg 13).

This is not found persuasive because the instant specification fails to provide guidance for making or isolating other nucleic acids encoding cysteine protease inhibitor comprising a type I thyroglobulin domain, or for making fragments of these proteins or of equistatin, that would work in the instant method. The specification also does not teach the structural features that distinguish from all the proteins comprising type I thyroglobulin domains, which will control insects by inhibiting cysteine proteases.

12. Claims 37-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the phrases "wherein at least one of the proteins ... is human p41 invariant chain fragment or a homologue or functional derivative thereof" in claim 37, "wherein at least one of the proteins ... is isolated from the sea anemone *Actina equina* and having the amino acid sequence SEQ ID NO:2 or a homologue or functional derivative thereof" in claim 38, and "wherein at least one of the proteins ... is a protein isolated from the eggs of chum salmon or a homologue or functional derivative thereof" in claim 39. Thus, such phrases constitute NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrases (*i.e.*, support for the use in the instant method of nucleic acids encoding those proteins) or to cancel the new matter.

13. Claims 10-13, 24, 28-33 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. Applicant's arguments filed 15 October 2002 have been fully considered but they are not persuasive.

Applicant urges that the claims have been amended to address the informality issues (response pg 13). This is not found persuasive because the following rejections are new, due to amendment of the claims:

Claim 10 lacks antecedent basis for the limitation " the reproduced plants" in line 4.

Claim 11 lacks antecedent basis for the limitation " the insect or nematode resistant plant " in part (b).

Claim 12 lacks antecedent basis for the limitation " the insect or nematode resistant progeny" in part (a).

In claim 13, the plants and the progeny should be claimed in the alternative.

Claims 28-29 are indefinite in their recitation of "DNA ... coding for ... a substantially pure protein". It is unclear what this means. Does it mean the expression vehicle encodes no other protein, even a selection marker?

Claim 30 is indefinite in its recitation of "causing the genome of the cells or tissue to produce a substantially pure polypeptide". A cell or tissue produces many proteins, including many proteins that must be produced simply to make the components of the transcription and translation machinery. It is unclear how a cell or tissue can produce a single protein.

Claims 24, 28-33 and 37-39 are indefinite in their recitation of "functional derivative thereof". The manner in which the derivative is functional is unclear. It is also unclear how the derivative differs from the original protein.

Claims 37-39 are indefinite in their recitation of "homologue". It is unclear how the homologue differs from the original protein.

Claim Rejections - 35 USC § 102

14. Claims 24, 28-33 and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Walsh et al (WO 9221753). The rejection is repeated for the reasons of record as set forth in the

Office action mailed 10 September 2002, as applied to claims 15 and 17. Applicant's arguments filed 15 October 2002 have been fully considered but they are not persuasive.

Applicant urges that the cysteine protease inhibitor of Walsh et al is not of the thyroglobulin family and is not a functional derivative of SEQ ID NO:2 (response pg 14-15).

This is not found persuasive because "functional derivative" is not defined. The protein taught by Walsh et al is a cysteine protease inhibitor, and would thus be a functional derivative of SEQ ID NO:2 or the other claimed cysteine protease inhibitors.

15. Claims 8, 10-14, 16-18, 27 and 34-36 are free of the prior art, given the failure of the prior art to teach or suggest a method of making a plant resistant to insects or nematodes by transformation with a nucleic acid encoding a cysteine protease inhibitor comprising a type I thyroglobulin domain.

Allowable Subject Matter

16. Claim 27 is allowable.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0196.

Anne R. Kubelik, Ph.D.
January 29, 2003

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